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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/911,588	07/24/2001	Michael S. Dobres	NOVA-0076	4361

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EXAMINER

HELMER, GEORGIA L

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 01/15/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/911,588

Applicant(s)

DOBRES ET AL.

Examiner

Georgia L. Helmer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 28-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 28-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13,17.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Restriction election

1. The Office acknowledges the receipt of Applicant's restriction election, Paper No. 16, filed 4 November 2002. Applicant elects Group I, claims 1-20 and 28-43, with traverse, saying that a search of Group I claims would overlap with that of Groups II and III claims. And that Groups I and II are classified in the same class and subclass. Applicant's traversal has been considered and is unpersuasive the class and subclass is not controlling, and different inventions may appropriately be classified in the same class, and also because even though the searches might overlap, they are not coextensive. Therefore, to search all these groups would constitute an undue burden on the Examiner. This restriction is made final. .

2. Claims 1-20 and 28-43 are pending, and are examined in the instant application. Claims 21-27, drawn to nonelected inventions, are withdrawn. This restriction is made FINAL.

Information Disclosure Statement

3. An initialed and dated copy of Applicant's IDS forms 1449, Paper No. 13, and 17, filed 15 May 2002, and 18 November 2002, respectively, are attached to the instant Office action.

Claim Rejections - 35 USC § 112-second

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-20 and 28-43 are rejected under 35 U.S.C. 112-2nd.

Claims 1 and 9 are drawn to a method for transforming a plant with a transgene, but no transgene is recited in the steps of the claims. The claims need to be amended to recite the starting material(s).

- Claim 1(a) recites "culturing an intact explant". Applicant defines "intact" in the specification (p 7) as meaning cells or tissue that have not been subjected to enzymatic digestion, or partial enzymatic digestion, of their cell walls. While applicant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). The term intact in claim 1 is used to mean cells/tissue not having been subjected to enzymatic digestion, or partial enzymatic digestion, of their cell walls while the accepted meaning is whole or undamaged. Since the claim refers to an "explant", which is by definition tissue removed from a plant, and thereby necessarily damaged, the use of "intact" with "explant" is contradictory. Applicant could obviate this rejection by reciting the specific limitation in the claim.
- "the explant" lacks antecedent basis.
- Claim 1 is an incomplete method, as the final step of the method does not produce the product claimed.

In claim 8 “gene” is unclear because a “gene” implies a DNA sequence that exists in nature and includes coding and noncoding regions, as well as all regulatory sequences associated with expression. Since this does not appear to be Applicant’s intention, the language “a DNA of interest” is suggested. Or Applicant may recite the various components of the “gene” desired. This rejection also is made to any recitation of a “transgene”. All subsequent recitations of “gene” or “transgene” are also rejected.

In claim 36, “modifies” the flowering response, is unclear because what the modification consists of is not described.

Claims 35-43, reciting names of specific genes, are rejected because just reciting the name does not define the metes and bounds of the genus encompassed by the claim. Also, just the recitation of a function or a structural feature of a gene does not define the metes and bounds of the genus encompassed by the claim.

Correction and /or clarification is required.

Claim Rejections - 35 USC § 112, first paragraph

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-19, and 30-43, are rejected under 35 U.S.C. 112, first paragraph, because the specification,

- while being enabling for a method of transforming a plant with a transgene, comprising (a) culturing an intact explant of chrysanthemum, rosa or petunia in nutritive medium, (b) electroporating the explant with a pulse length of at least about 50 milliseconds but not more than 800 milliseconds, to produce a transformed explant; wherein the transgene is stably integrated into a chromosome of a cell of the transformed explant, does not reasonably provide enablement
- for a method where the plant is a monocot or gymnosperm.

Enablement is considered in view of the *Wands* factors (MPEP 2164.01(a)). The Wands factors are

- *The nature of the invention and the breadth of the claims.* Applicant's claims are drawn to a method of transforming a plant with a transgene, comprising (a) culturing an intact explant of the plant in nutritive medium, (b) electroporating the explant with a pulse length of at least about 50 milliseconds to produce a transformed explant; wherein the transgene is stably integrated into a chromosome of a cell of the transformed explant; to pulse lengths of 50-500 milliseconds, to two transgenes electroporated, and to a marker gene also electroporated, where the marker is on a second piece of DNA, to plants lacking a marker gene, to marker genes including IPT, to any plant, including dicot, monocot, and gymnosperm plants, also chrysanthemum, petunia and rose plants, to the NPT selectable marker, the CONSTANS gene, transgene modifying the flowering response, a member of the GATA1 family of transcription

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factors, zinc-finger containing transcription factors, the GAI gene and genes for gibberellin signaling proteins, SH2-like transcription factors, transcription factors, and transgenes comprising a signal transduction domain.

- *The amount of guidance given, and the presence of working examples.* The physiological art in general is acknowledged to be unpredictable (MPEP 2164.03).

Applicant gives four examples: Example 1, of electroporation of chrysanthemum leaf explants with a gus gene and a NPT gene, producing gus-positive and kanamycin-resistant tissue.

Example 2, a prophetic example of electroporation of chrysanthemum leaf explants with three independent genes—the GAI gene, the CONSTANS gene and a selectable marker. Transgenic tissue is not produced in this example.

Example 3, of electroporation of petunia callus with a gus gene and a NPT gene, producing kanamycin-resistant tissue.

Example 6, of electroporation of Rosa petioles, with IPT gene, producing tissue which is phenotypically similar to the expected transformed tissue, however without any biochemical or molecular characterization.

The state of the art and the predictability thereof. Applicant claims all plants, including dicot, monocot, and gymnosperm plants. Applicant teaches chrysanthemum, petunia and rose plants. The state of the art is that while one skilled in the art of tissue culture and transformation can make explants of tissue, culture and regenerate the explants, guidance is needed as to what kind of explant

would function as desired, while maintaining post -electroporation health and the ability to be regenerated. No one system works for all plants. Each system requires optimization (Hansen et al, Recent advances in the transformation of plants. Trends in Plant Science, vol 4, No. 6, pages 226-231, 1999). It is unpredictable that systems developed for dicots, petunias and chrysanthemum, could be used for be for monocots or gymnosperms, with a reasonable expectation of success. Lacking guidance for monocot or gymnosperms systems, one skilled in the art would need to do random trial and error experimentation, which would require undue experimentation to make and/or use the claimed invention.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-17, 19, 20, 28 and 30-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Dev et al, US 5,859,327 issued January 12, 1999.

Dev teaches a method for transforming a plant (Abstract, and col 10, lines 23-27) with a transgene, comprising the steps of culturing an intact explant (col 12, line 29) in nutritive medium (col 15, lines 60-66), electroporating the explant with a pulse length of about 50 milliseconds (col 8, lines 58-61 and 65) , to produce a transformed explant, where in the transgene is stably integrated ((Abstract, and col 10, lines 23-27). Dev also teaches a pulse length of 90-250 milliseconds (col 16, lines 40-55), 90-200 ms, and 90-150 (col 16, lines 40-55), and a petunia explant (col 14, lines 66-67). Dev also teaches transformation with at least one structural gene (claim 6, for example) and transformation with a marker gene (claim 10, for example).

Accordingly, Dev anticipates the claimed invention.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1-20 and 28-43 rejected under 35 U.S.C. 103(a) as being unpatentable over Dev as discussed above, and further in view of Applicants admitted prior art.

Claims 1-17, 19, 20, 28 and 30-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Dev discussed supra.

The teachings of Dev are discussed above. Dev does not teach an IPT gene, the CONSTANS gene, a transgene modifying the flowering response, a member of the GATA1 family of transcription factors, zinc-finger containing transcription factors, the GAI gene and genes for gibberellin signaling proteins, SH2-like transcription factors, transcription factors, and transgenes comprising a signal transduction domain.

Applicants admitted prior art (p22) teaches the CONSTANS gene, a transgene modifying the flowering response, a member of the GATA1 family of transcription factors, zinc-finger containing transcription factors, the GAI gene and genes for gibberellin signaling proteins, SH2-like transcription factors, transcription factors, and transgenes comprising a signal transduction domain. IPT genes for transformation were known as taught at the paragraph bridging pages 14-15.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to substitute the NPT gene of Dev with the CONSTANS gene, a transgene modifying the flowering response, a member of the GATA1 family of transcription factors, zinc-finger containing transcription factors, the GAI gene and genes for gibberellin signaling proteins, SH2-like transcription factors, transcription factors, or transgenes comprising a signal transduction domain, or the IPT gene, of Applicant's admitted prior art, for the purpose of , enhancing and controlling the flowering and stalk height characteristics of the ornamental plants taught by Dev. And

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the number of transgenes or the particular selectable marker would have been a matter of choice. One skilled in the art would have been motivated to generate the claimed invention with a reasonable expectation of success.

Remarks

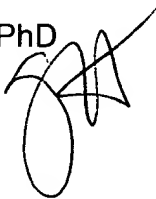
12. No claim is allowed.

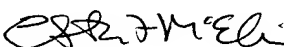
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Georgia Helmer PhD
Patent Examiner
Art Group 1638
January 9, 2003




ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1600